

DETAILED ACTION

I. This Office is responsive to Applicant's response filed 6-6-11. Claims 36-39 are cancelled. Claims 3-14, 18-27, 34, and 46-47 are amended. Claims 54-55 is new. Claims 1-35 and 40-55 are pending.

Election/Restrictions

II. Restriction is required under 35 U.S.C. 121 and 372.

III. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I: claims 1-8, 12-14, and 23-27 drawn to a composition comprising a polypeptide which comprises a sequence selected from the group consisting of surface-located Campylobacter polypeptides of SEQ ID NO:1-51, or comprises an antigenic fragment or variant of said sequence.
2. Group II: claims 1, 15-27, and 28-31, drawn to a composition comprising an antibody capable of binding polypeptide which comprises a sequence selected from the group consisting of surface-located Campylobacter polypeptides of SEQ ID NO:1-51, for use as a medicament; drawn to an antibody capable of binding a polypeptide selected from the group consisting of SEQ ID NO: 1-36.
3. Group III: claims 1, 9-11, 23-27, 32, and 34-35, drawn to a composition comprising a polynucleotide comprising a sequence encoding the polypeptide which comprises a sequence selected from the group consisting of surface-located Campylobacter polypeptides of SEQ ID NO:1-51, an expression vector comprising a sequence encoding said polypeptide, a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector; a recombinant cell transformed or transfected with a polynucleotide comprising a sequence encoding a polypeptide, said polypeptide comprising a sequence selected from the group consisting of SEQ ID NO: 1-36, or comprising an antigenic fragment or variant of said

- sequence; a recombinant attenuated or reduced-virulence Escherichia coli or recombinant attenuated or reduced-virulence Salmonella cell transformed or transfected with a polynucleotide comprising a sequence encoding a polypeptide, said polypeptide comprising a sequence selected from the group consisting of SEQ ID NO:37-51, or comprising an antigenic fragment or variant of said sequence.
4. Group IV: claim 40 and 42 drawn to a method for raising antibodies to a polypeptide selected from the group consisting of SEQ ID NO: 1-36 in a non-human animal comprising the steps of providing a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO:1-36, or comprising an antigenic fragment or variant of said sequence, a polynucleotide comprising a sequence encoding said polypeptide, an expression vector comprising a sequence encoding said polypeptide, or a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector, introducing a composition comprising said polypeptide, polynucleotide, vector, recombinant virus or recombinant cell into said animal, raising antibodies in said animal, and isolating and optionally purifying the antibodies.
5. Group V: claim 41 and 42 drawn to a method for raising antibodies to a polypeptide selected from the group consisting of SEQ ID NO:37-51 in an non-human animal, wherein the antibodies are capable of binding an intact Campylobacter jejuni cell, the method comprising the steps of providing a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO:37-51, or comprising antigenic fragment or variant of said sequence, a polynucleotide comprising a sequence encoding said polypeptide, an expression vector comprising a sequence encoding said polypeptide, a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector, introducing a composition comprising said polypeptide, polynucleotide, vector, recombinant virus or recombinant cell into said animal, raising antibodies in said animal, isolating and optionally purifying the antibodies, and selecting antibodies capable of binding an intact Campylobacter jejuni cell.
6. Group VI: claims 43-44 and 46-47 drawn to a method for detecting Campylobacter jejuni or parts thereof in a sample comprising the steps of a. contacting said sample with an indicator moiety capable of specifically binding a polypeptide selected from the group consisting of SEQ ID NO: 1-36, and b. determining whether a signal has been generated by the indicator

- moiety, thereby detecting whether said sample contains *Campylobacter jejuni* or parts thereof.
7. Group VII: claim 45 drawn to a method for detecting *Campylobacter jejuni* in a sample comprising the steps of a. contacting said sample with an indicator moiety capable of specifically binding a polypeptide selected from the group consisting of SEQ ID NO:37-51, wherein the indicator moiety furthermore is capable of specifically binding intact *Campylobacter jejuni* cells, and b. determining whether a signal has been generated by the indicator moiety, thereby detecting whether said sample contains *Campylobacter jejuni*
 8. Group VIII: claim 48 drawn to a method for identifying a binding partner of a polypeptide selected from the group consisting of SEQ ID NO: 1-36 or a fragment thereof, comprising the steps of a. providing a polypeptide selected from the group consisting of SEQ ID NO:1-36 or a fragment thereof, b. contacting said polypeptide or fragment with a putative binding partner, and c. determining whether said putative binding partner is capable of binding to said polypeptide or fragment.
 9. Group IX: claim 49 drawn to a method for identifying a compound with antibacterial activity against *Campylobacter jejuni* comprising the steps of a. providing a sensitised cell which has a reduced level of a polypeptide selected from the group consisting of SEQ ID NO: 1-36, and b. determining the sensitivity of said cell to a putative antibacterial compound, for instance by a growth assay.
 10. Group X: claim 50 drawn to a method for identifying a compound with antibacterial activity against *Campylobacter jejuni* comprising the steps of a. providing a sensitized cell which has a reduced level of a polypeptide selected from the group consisting of SEQ ID NO:37-51, and b. determining the sensitivity of said cell to a putative antibacterial compound, for instance by a growth assay, wherein the putative antibacterial compound is not capable of passing through the outer-membrane of a wild-type *Campylobacter jejuni* cell.
 11. Group XI: claims 51-52 drawn to a method for identifying an inhibitor of a polypeptide selected from the group consisting of SEQ ID NO: 1-36, comprising the steps of a. providing two cells which differ in the level of a polypeptide selected from the group consisting of SEQ ID NO: 1-36, b. determining the sensitivity of said cells to a putative inhibitor, for instance

- by a growth assay, and c. determining whether said two cells are differently affected by the presence of said putative inhibitor.
12. Group XII: claim 53 drawn to a method for identifying an inhibitor of a polypeptide selected from the group consisting of the polypeptides of SEQ ID NO:37-51, comprising the steps of a. providing two cells which differ in the level of a polypeptide selected from the group consisting of SEQ ID NO:37-51, b. determining the sensitivity of said cells to a putative inhibitor, for instance by a growth assay, wherein the putative inhibitor is not capable of passing through the outer membrane of a *Campylobacter jejuni* cell, and c. determining whether said two cells are differently affected by the presence of said putative inhibitor.
13. Group XIII: claims 54-55 drawn to a method for treatment or prevention of *Campylobacter jejuni* infection in an animal or human being comprising the step of administering any one of the following a. a polypeptide which comprises any of the sequences of SEQ ID NO:1-51, such as any of the sequences of SEQ ID NO:1-36 or any of SEQ ID NO:37-51, or comprises a fragment or variant of any of said sequences, b. a polynucleotide comprising a sequence encoding said polypeptide c. an expression vector comprising a sequence encoding said polypeptide, d. a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector, or e. an antibody capable of specifically binding said polypeptide, thereby treating or preventing a *Campylobacter jejuni* infections in said animal or human being; a method a method for the immunization of an animal or human being against *Campylobacter jejuni* infections comprising the step of administrating a. a polypeptide which comprises a sequence selected from the group consisting of SEQ ID NO:1-51, such as any of the sequences of SEQ ID NO:1-36 or any of SEQ ID NO:37-51, or comprises an antigenic fragment or variant of any of said sequences, b. a polynucleotide comprising a sequence encoding said polypeptide, c. an expression vector comprising a sequence encoding said polypeptide, or d. a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector.
14. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of linking the various groups is drawn to a composition comprising a polypeptide which comprises a sequence selected from the group consisting of surface-located *Campylobacter* polypeptides of SEQ ID NO:1-51, or comprises an antigenic fragment or variant of said sequence. The technical feature of Group I is anticipated by (Kleanthous et al WO9843478-A1 Publication Date October 8, 1998) by teaching an antigenic fragment of SEQ ID NO: 6 (see claims 8-11 and STIC search) which necessarily teach a composition comprising a antigenic fragment or variant of said sequence of surface-located *Campylobacter* polypeptide of SEQ ID NO:6.

Group I lacks unity with Groups II-XIII, because the technical feature of Group I is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

**Consequently, the instant invention does not make a contribution over the art.
Hence there is no unity of invention.**

Sequence Election Requirement Applicable to All Groups

15. The Groups I-XIII read on SEQ ID NOs: 1-51 encompassing patentably distinct sequence(s) in the claims. Each sequence is patentably distinct because the sequences are structurally unrelated, and a further restriction is applied to each various groups (see below). Applicant must elect a specific SEQ ID NO., if applicable. (See MPEP 803.04).

Applicant is advised that examination will be restricted to only the elected the formula (if applicable) and should not to be construed as a species election.

Election Requirement Applicable to Groups V and XIII

16. The Groups V and XIII read on a Markush group comprising at least one or all of the following below. The claims encompass a polypeptide, polynucleotide, and/or an antibody which are patentably distinct encompassed in the claims. Applicant must elect a specific invention of the following below of A. B. and C.

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- A. a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO:1-36, or comprising an antigenic fragment or variant of said sequence.
- B. a polynucleotide comprising a sequence encoding said polypeptide, an expression vector comprising a sequence encoding said polypeptide and a recombinant virus or recombinant cell comprising said polynucleotide or said expression vector.
- C. an antibody capable of specifically binding said polypeptide, thereby treating or preventing a *Campylobacter jejuni* infections in said animal or human being.

If Applicants elect A. B. or C. Applicant must further a SEQ ID NO. from SEQ ID NOs: 1-51 encompassing patentably distinct sequence(s) encompassed in the claims. Each sequence is patentably distinct because the sequences are structurally unrelated, and a further restriction is applied to each various groups (see below). Therefore Applicant must further elect a specific SEQ ID NO. (i.e. see claims 40, and 54, 55), if applicable. (See MPEP 803.04).

Applicant is advised that examination will be restricted to only the elected the formula (if applicable) and should not to be construed as a species election.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is

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provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Archie whose telephone number is 571-272-9938. The examiner can normally be reached on M-F 8:30am-5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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GAU 1645
REM 3B31

/Gary B. Nickol /

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